510(K) SUMMARY

Premarket Notification for the I-MAX Touch K083057

JUN - 2 2009

Identification

Applicant	OWANDY 6 Allee Kepler 77420 Champs sur Marne - France
Contact person	Olivier DEROO, Quality and Regulations Manager
Email	oderoo@owandy.com

TRADE NAME : I-MAX Touch (PAN and CEPH)
Common name : Extra oral source X-Ray System
Classification : according to 21CFR872-1800 , I-MAX Touch is in class 2

Intended use
The I-MAX Touch (PAN and CEPH) is intented for dental radiographic examination of the teeth and specifically for panoramic examinations, TMJ studies, implantology and Cephalometry.
It is to be only used by dental practitioners and/or radiologists.

Substantial equivalence and technological characteristics
The I-MAX Touch is defined as substantially equivalent to the STRATO 2000 D, manufactured by VILLA SISTEMI MEDICALI (X-ray system) and OWANDY (digital acquisition device) and cleared by FDA with K002432 (VILLA) and K041120 (OWANDY). See comparison table in Chapter 3.
The following table compares the two units :

Trade Name	I-Max Touch	Strato 2000 D
K number	K083057	K002432+K041120
Intended use	extra-oral source X-ray system for dental radiographic examination of the teeth and specifically for panoramic examinations, TMJ studies and Cephalometry.	extra-oral source X-ray system for dental radiographic examination of the teeth and specifically for panoramic examinations, TMJ studies, implantology and Cephalometry.
CEPH option	Yes	Yes
Digital acquisition Sensor	CCD	CCD
Computer Interface Board	Ethernet	USB
Digital Storage	USB memory stick	Compact flash card
High voltage value	86 KVp max	80 KVp max
Tube current	12 mA max	12 mA max
Total filtration	2.5 mmAl	2.5 mmAl

Examination programs	Adult / Child selection Small / Medium / Large size selection Standard panoramic Right Semi-Panoramic Left Semi-Panoramic Panoramic with improved orthogonality Reduced dose panoramic Incisor block panoramic TMJ Maxillary sinus Lateral Ceph Frontal Ceph Carpus	Adult / Child selection Small / Medium / Large size selection Standard panoramic Right Semi-Panoramic Left Semi-Panoramic Panoramic with improved orthogonality Reduced dose panoramic Incisor block TMJ Maxillary sinus Lateral Ceph Frontal Ceph Carpus
X-ray exposure timing	13,8 Sec PAN adult, CEPH exposure time variable according to the type of resolution and format selected. Max 15 sec	15 Sec PAN adult, CEPH exposure time variable according to the type of resolution and format selected. Max 15 sec
Electrical characteristics	6,6 A at 230V 50/60 Hz	18 A at 110V
Positioning lights	Class 1 laser according to EN60825-1+A1+A2	Class 2 laser
Focus receptor distance	500 mm	512 mm
Minimum room size	2450X2000X1450	2320X1900X1300

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OWANDY
% Mr. Claude Berthouin
Official Correspondent
Denterprise International, Inc.
RF America, Inc.
110 W. Granada Blvd., Suite 207
ORMOND BEACH FL 32176

JUN - 2 2009

Re: K083057
Trade/Device Name: I-Max Touch
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: April 10, 2009
Received: April 13, 2009

Dear Mr. Berthouin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

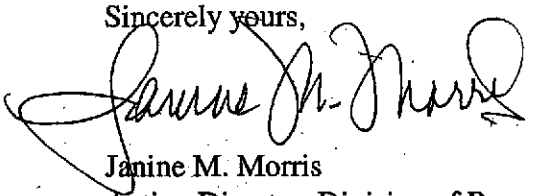
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

Applicant: OWANDY

510(k) Number : K083057

Device Name: I-Max Touch

Indication For Use:
The I-Max Touch (PAN and Ceph) is a digital image acquisition system to be used in conjunction with a Villa Sistemi Medicali Digital Panoramic X-ray System, such as I-Max Plus or Strato D, to capture images by a sensor, digitalize the image, review images and format images to be sent to a PC, according to a standard protocol, through the existing acquisition board of panoramic system.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083057